

Ethical Guidelines for Human Genome/Gene Analysis Research

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Ministry of Education, Culture, Sports, Science and Technology

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Preamble

The promotion of scientific research is an important issue for achieving a society in which people can live healthy and fulfilling lives. In this context, human genome/gene analysis research begun in the latter half of the twentieth century has made significant contributions to the progress of both life science and health care science and is starting to play an important role in the development of the health and welfare of humanity and in the growth of new industries.

It is also true that human genome/gene analysis research depends largely on research activities targeted at individuals, and that genetic information obtained in the course of research reveals genetic predispositions of both donors (those persons who provide a human specimen for human genome/gene analysis research) and their blood relatives, which might cause various ethical, legal or social problems. Therefore, research must be conducted properly on the basis of respect for human dignity and human rights as well as understanding and cooperation from society. For these purposes, guaranteeing the rights of individual donors should be given priority over scientific or societal benefits in accordance with ethical standards stipulated in such documents as the World Medical Association's Declaration of Helsinki. It is also essential that society be given adequate explanation on this aspect of research, and that research be conducted on the basis of this understanding.

These Guidelines were jointly prepared by the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare and the Ministry of Economy, Trade and Industry, and are presented to society at large as ethical guidelines to be universally applied to human genome/gene analysis research. They have been prepared based on the general principles expressed in the "Fundamental Principles of Research on the Human Genome" (issued by the Bioethics Committee of the Council for Science and Technology on June 14, 2000), which in turn was established based on such documents as the "Universal Declaration on the Human Genome and Human Rights" adopted by the United Nations Educational, Scientific and Cultural Organization (UNESCO), and also with reference to such documents as the "Guidelines for Bioethical Problems Associated with Genetic Analysis Research" (from the Advanced Medical Technology Evaluation Committee of the Health Sciences Council on April 28, 2000), UNESCO's "International Declaration on Human Genetic Data" and the "Act on the Protection of Personal Information" (Act No. 57 of 2003).

Any and all parties who are involved in human genome/gene analysis research are required to comply with these Guidelines.

With respect to the protection of personal information, any institution conducting human genome/gene analysis research shall give heed to the requirement for them to observe the Act on the Protection of Personal Information, the Act on the Protection of Personal Information Held by Administrative Organs (Act No. 58 of 2003), the Act on the Protection of Personal Information Held by Independent Administrative Agencies, etc.

(Act No. 59 of 2003), and prefectural and municipal ordinances established by local government in accordance with the aim of Article 11(1) of the Act on the Protection of Personal Information, applied according to such categories as private-sector enterprises, administrative organs and incorporated administrative agencies, etc.

PART I: BASIC IDEAS

1. Basic Principles

Given the special characteristics of human genome/gene analysis, such as that genetic information can be obtained in the course of such analysis, these Guidelines were established as ethical guidelines to be applied to all human genome/gene analysis research and to be observed in every research locale. The purpose of these Guidelines is for human dignity and human rights to be respected and for research to be promoted properly based on an understanding and cooperation of society. Thus, the following matters have been set as the basic principles of these Guidelines:

- (1) Respect for human dignity
- (2) Adequate prior explanation and consent on the basis of free will (informed consent)
- (3) Thorough protection of personal information
- (4) Conduct of socially beneficial research that contributes to the intellectual foundation, health and welfare of humanity
- (5) Priority of guaranteeing individual human rights over scientific or societal benefits
- (6) Guarantee of the propriety of research through preparation of and compliance with research protocols pursuant to these Guidelines as well as prior review and authorization by the ethics review committee established as an independent body
- (7) Guarantee of the transparency of research, through on-site investigation of research progress by third parties as well as through the disclosure of research results
- (8) Advancement of the understanding of the public and society such as through campaigns to promote public awareness about human genome/gene analysis research, and dialogue with the public conducted based on the content of the research

<Note>

Recognizing the distinctive characteristic of human genome/gene analysis research—that is, that various problems might be raised as a result of the risk of genetic information obtained in the course of research possibly revealing genetic predispositions of both donors and their blood relatives, or of the potential for the research to possibly go beyond just issues for an individual donor and characterize the properties of the group to which that donor belongs—the definitions and scope of research to which these Guidelines should apply are stipulated in paragraph 16(3) of Part VI.

2. Scope of Application

- (1) These Guidelines shall apply to human genome/gene analysis research and require researchers, etc. involved in that research to comply with them. In order for research to be conducted properly, in addition to each and every researcher, etc. making efforts to this end, it is also important that an organizational structure and environment, needed

for the appropriate protection of personal information and appropriate ethical conduct, be put in place at the research institution.

The issue of clinical examinations or equivalent human genome/gene analyses which are conducted in the course of a medical treatment and whose analytical results are medically established as instruments to be utilized directly for the medical treatment of donors and their blood relatives will have to be carefully discussed in the future as a matter regarding medical treatment, and these Guidelines therefore do not apply.

However, with regard to these human genome/gene analyses, along with observing guidelines for the appropriate handling of personal information at medical care and nursing care providers pursuant to the Act on the Protection of Personal Information, medical doctors giving treatment should be responsible for taking appropriate measures based on the purposes of these Guidelines, referring to guidelines etc. prepared by pertinent academic societies or other authorized organizations.

(2) These Guidelines shall not apply to any ongoing human genome/gene analysis research begun prior to the enforcement of the Ethical Guidelines for Human Genome/Gene Analysis Research (Public Notice No. 1 of the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare and the Ministry of Economy, Trade and Industry, 2001; hereinafter referred to as “the former guidelines”).

<Detailed regulations concerning research conducted prior to the enforcement of the former guidelines>

Although these Guidelines do not apply to ongoing human genome/gene analysis research begun prior to the enforcement of the former guidelines, after the effective date of the Act on the Protection of Personal Information, such research will need to be conducted in accordance with that Act.

<Note>

The effective date of the former guidelines is April 1, 2001.

3. Personal Information Subject to Protection

(1) The term “personal information” shall mean information about a living individual which can identify the specific individual by name, date of birth or other description contained in such information (including such information as will allow reference to other information and will thereby enable the identification of the specific individual).

(2) Information, whereby personal information has been anonymized in an unlinkable fashion, shall not fall under personal information. Information, whereby personal information has been anonymized in a linkable fashion, shall not fall under personal information as long as the research institution does not possess an index table of other

assigned symbols, numbers or the like, such that the said information could be linked to the individual pertaining to the personal information.

<Detailed regulations concerning the handling of information that has been anonymized in a linkable fashion>

When information anonymized in a linkable fashion is handled by research divisions within the same corporation or administrative organ, security control measures may be established for the relevant research divisions so that adequate security control can be ensured across the entire organization, for instance, providing appropriate measures in view of such circumstances as anonymization is conducted outside the research division and the index table of the anonymized information is strictly controlled.

(3) Even if information handled in human genome/gene analysis research does not fall under personal information, any genetic information, medical information or other information that reflects the characteristics or constitution of an individual shall be handled appropriately in accordance with these Guidelines.

4. Collaborative Research with Overseas Institutions

(1) In cases where a Japanese research institution conducts collaborative research with an overseas research institution, it shall conduct the collaborative research while paying careful attention that human dignity and human rights are also respected when human specimens are donated and human genome/gene analysis research conducted in the country where the collaborative research is conducted.

(2) In cases where a research institution in Japan conducts collaborative research with an overseas research institution, it shall, in principle, conduct the research in accordance with these Guidelines while also observing the laws, regulations, guidelines and so forth stipulated in the country where the collaborative research is conducted.

However, in the following cases, the research institution may accept donations of human specimens and handle human specimens in the other country by observing the standards set forth in the laws, regulations, guidelines and so forth stipulated in the other country:

(a) When these Guidelines are more rigorous than the standards in the other country, and when both of the following conditions are met:

(i) Application of these Guidelines is difficult in the other country.

(ii) With the authorization of the ethics review committee of the Japanese research institution, the director of the said institution has determined it appropriate to properly action the matters specified in the detailed regulations.

(b) When the standards in the other country are more rigorous than these Guidelines.

<Detailed regulations when conducting collaborative research with overseas research institutions>

1. The matters prescribed in paragraph 4(2)(a)(ii) of Part I shall be as follows:

- (1) Informed consent is obtained
- (2) Appropriate measures are taken for the protection of personal information of donors
- (3) Regarding the scientific and ethical propriety of research protocols, authorization is given by the other country, or authorization is given by an ethics review committee or equivalent organization within the institution in the other country based on the laws, regulations, guidelines and so forth, and approval is given by the director of the research institution in the other country.

2. In the case set forth in paragraph 4(2)(b) of Part I, research shall be conducted in line with the standards in the other country.

PART II: RESPONSIBILITIES OF RESEARCHERS, ETC.

5. Basic Responsibilities of All Researchers, etc.

(1) All researchers, etc. shall conduct human genome/gene analysis research for such purposes as elucidating life phenomena, preventing diseases, improving diagnosis and treatment protocols, and promoting health.

(2) All researchers, etc. shall ensure the societal usefulness of their human genome/gene analysis research and shall pay attention to guaranteeing the human rights of individuals by prioritizing them over scientific or societal benefits.

(3) All researchers, etc. shall make it a basic practice to conduct human genome/gene analysis research only after obtaining the informed consent of donors or proxy consenters, etc.

(4) All researchers, etc. shall not, in the absence of any justifiable reason, divulge personal information obtained in the course of their duties. This shall continue to apply after they resign their position.

(5) All researchers, etc. shall endeavor to protect personal information and shall also respond in good faith to questions, complaints, etc. concerning the handling of personal information.

(6) All researchers, etc. shall, when any serious concerns arise in terms of guaranteeing the human rights of donors, etc., such as an unexpected divulgence of personal information, immediately report this to both the director of their research institution and to a research director.

(7) All researchers, etc. shall conduct human genome/gene analysis research properly in compliance with these Guidelines and with respect for human dignity and human rights by, for instance, conducting research in accordance with a research protocol as

authorized by the ethics review committee and approved by the director of their research institution.

(8) All researchers, etc. shall endeavor to guarantee the transparency of their research through, for instance, ensuring due process when conducting research, on-site investigations by outside experts, appropriate responses to inquiries from donors, etc. regarding the progress of research, and the release of research results into the public domain.

(9) All researchers, etc. shall, in consideration of the fact that the donation of human specimens is based on goodwill, make efforts to minimize the amount of human specimens donated by people by, for instance, properly preserving and utilizing those specimens already provided.

(10) No researchers, etc. shall, when conducting human genome/gene analysis research, acquire personal information or human specimen by deception or other wrongful means.

6. Responsibilities of Directors of Research Institutions

(1) The director of a research institution shall assume ultimate responsibility for the conduct of human genome/gene analysis research in their institution, and shall oversee research directors and research investigators so that they conduct research properly in accordance with a research protocol. In doing so, the director of the research institution shall endeavor to have all researchers, etc. at their institution understand thoroughly that they should guarantee the human rights of donors, etc. as much as possible and that they may be subject to adverse disposition, such as disciplinary action, if they violate these Guidelines, a research protocol or the like.

(2) The director of a research institution may, pursuant to the rules stipulated by the institution, delegate the authority or affairs prescribed in these Guidelines to an appropriate person in the institution.

<Detailed regulations concerning delegation of the authority or affairs prescribed in these Guidelines>

1. The director of a research institution may, in an effort for the smooth and flexible conduct of human genome/gene analysis research, delegate all or part of the authority or affairs prescribed in these Guidelines by designating a person with overarching responsibility.

2. The term “a person with overarching responsibility” is someone who gives orders necessary for supervision to research directors, etc. and supervises the whole research, and includes, for instance:

- In the case of a university hospital, the hospital director

- In the case of a health center, the health center director
- In the case of a faculty of medicine at a university, the faculty dean
- In the case of a corporate research laboratory, the laboratory director

3. In cases where research and the collection of human specimens are conducted within the same corporation or administrative organ, the authority or affairs may be delegated by designating a person with overarching responsibility for each operation.

(3) The director of a research institution shall take systematic, human, physical and technological security control measures to prevent any divulgence, loss or damage of the personal information it handles and to otherwise control the security of personal information.

Also, the director of a research institution shall, when having researchers, etc. handle personal information, exercise necessary and appropriate supervision over the researchers, etc. to ensure the security control of the personal information.

<Detailed regulations concerning security control measures>

The term “systematic, human, physical and technological security control measures” is a requirement for measures that are necessary and appropriate according to the nature of the information handled.

1. Systematic security control measures

The term “systematic security control measures” shall mean clearly stipulating the responsibilities and authority of researchers, etc. for security control, providing and implementing rules and procedures manuals for security control (hereinafter referred to as “rules, etc.”), and keeping track of the implementation thereof. Systematic security control measures include the following matters:

- (i) Establishment of an organizational structure for implementing security control measures for personal information
- (ii) Provision of rules, etc. stipulating the security control measures for personal information, and operation in accordance with those rules, etc.
- (iii) Establishment of means for summarizing how personal information is being handled
- (iv) Assessment, revision and improvement of security control measures for personal information
- (v) Courses of action for dealing with accidents or violations

2. Human security control measures

The term “human security control measures” shall mean concluding nondisclosure agreements with researchers, etc. for personal information designated as business in confidence, and conducting education and training for them. Human security control measures include the following matters:

- (i) Conclusion of nondisclosure agreements at the time of entering an employment contract or entrustment contract
- (ii) Provision of education and training for researchers, etc.

3. Physical security control measures

The term “physical security control measures” shall mean such measures as controlling the entering and leaving buildings or rooms, and preventing the theft of personal information. Physical security control measures include the following matters:

- (i) Controlling the entering and leaving buildings or rooms
- (ii) Prevention of theft, etc.
- (iii) Physical safeguarding of equipment, apparatus, etc.

4. Technological security control measures

The term “technological security control measures” shall mean technology-based measures for controlling the security of personal information, such as access controls to personal information and to information systems that deal with such information, measures against unauthorized software, and the monitoring of information systems. Technological security control measures include the following matters:

- (i) Identification and authentication for accessing personal information
- (ii) Access controls to personal information
- (iii) Management of access rights to personal information
- (iv) Records of access to personal information
- (v) Measures against unauthorized software for information systems that deal with personal information
- (vi) Measures when transferring or otherwise communicating personal information
- (vii) Measures when checking the operation of information systems that deal with personal information
- (viii) Monitoring of information systems that deal with personal information

(4) In consideration of the human dignity of a deceased person, the feelings of their bereaved family members, and the fact that genetic information is common to their blood relatives, the director of a research institution shall also implement systematic, human, physical and technological security control measures for the security control of the personal information of deceased persons in the same way as information about a living individual.

(5) The director of a research institution shall implement appropriate measures when handling anonymized information that does not fall under personal information, such as making researchers, etc. understand thoroughly the importance of managing such information appropriately, managing such information (including responses to accidents, etc.), clarifying responsibilities, and preventing the handling of such information by persons other than researchers, etc.

<Detailed regulations concerning the handling of anonymized information>

When handling anonymized information that does not fall under personal information, the director of the research institution shall implement appropriate measures, taking care to discern between linkable and unlinkable information.

(6) When entrusting all or part of the handling of information relating to the business of human genome/gene analysis research, the director of the research institution shall

exercise necessary and appropriate supervision over the entrusted person to ensure the security control of any personal information that they have been entrusted to handle, and to ensure the appropriate handling of any anonymized information that does not fall under personal information.

<Detailed regulations concerning the supervision of entrusted persons>

The term “necessary and appropriate supervision over the entrusted person” shall mean, for instance, explicitly prescribing the content of the security control measures stipulated by the entruster in the entrustment contract and confirming whether such content is being observed.

(7) When handling personal information in human genome/gene analysis research, the director of the research institution shall assign a privacy officer for the purpose of protecting the personal information. Upon clearly defining the responsibilities, authority and a clear-cut chain of command, the director may, as required, also designate a person who performs a portion of the work of the privacy officer (hereinafter referred to as a “privacy subofficer”), or assistants who conduct actual operations under the supervision of a privacy officer or privacy subofficer.

<Detailed regulations concerning the requirements for privacy officers>

Privacy officers and privacy subofficers shall be persons (medical doctors, pharmacists, etc.) who are prohibited from divulging any confidential information obtained in the course of their duties under Article 134 of the Penal Code (Act No. 45 of 1907), Article 100 of the National Public Service Act (Act No. 120 of 1947) or any other law.

A privacy officer or privacy subofficer may not simultaneously hold the position of a research director or research investigator who conducts human genome/gene analysis research (excluding the provision of human specimens) using human specimens provided by that privacy officer or privacy subofficer.

(8) The director of a research institution shall establish an ethics review committee as an advisory body to review the propriety of conducting human genome/gene analysis research, etc.

When, however, it is difficult to set up an ethics review committee for reasons such as the small size of the human specimen collecting institution, this committee may be substituted with an ethics review committee established by a collaborative research institution, a general incorporated association, a general incorporated foundation or an academic society.

<Detailed regulations concerning the establishment of ethics review committees>

Where a similar committee, which has already been established in a research institution, is reorganized as an ethics review committee that satisfies these Guidelines, its name shall not matter.

(9) In determining whether or not to approve a research protocol or alteration thereof, the director of the research institution shall always respect the opinions of the ethics review committee. In this case, the director shall not approve the conduct of any research for which the ethics review committee has submitted an opinion expressing disapproval.

(10) When conducting collaborative research within Japan, the director of the research institution shall obtain approval for the research protocol from the ethics review committees established in each research institution, after first presenting such information as the status of approval for the research protocol at the other collaborative research institutions, the status of informed consent and the status of anonymization.

However, in the case of collaborative research in which multiple institutions participate, where the principal institution conducting the research is in charge of promoting and managing the overall research, a review of all research protocols may be performed by the ethics review committee established within the principal research institution, with fast-track reviews being conducted at the other collaborative research institutions on the conduct of research protocols in accordance with paragraph 9(5) of Part II.

(11) The director of a research institution shall keep track of the progress of human genome/gene analysis research by, for instance, receiving research progress reports from research directors on a regular basis, at least annually, and having on-site investigations conducted by outside experts on a regular basis, at least annually, and shall order the research be altered or discontinued based on the ethics review committee expressing an opinion of alteration or discontinuation, or if necessary for any reason.

<Detailed regulations concerning on-site investigations by outside experts>

1. The director of a research institution shall, with regard to the state of the procedures for obtaining informed consent and the state of personal information protection, have on-site investigations conducted to check that they are being conducted in accordance with the relevant research protocol.

2. The director of a research institution shall have research directors and research investigators cooperate with on-site investigations.

3. External investigators shall not, in the absence of any justifiable reason, divulge information obtained in the course of an on-site investigation. This shall continue to apply after they resign their position.

(12) The director of a research institution shall deliver to its privacy officers a copy of an approved research protocol, a copy of regular reports regarding research progress and a copy of the results of on-site investigations conducted by outside experts.

(13) The director of a research institution shall deliver to the ethics review committee a copy of regular reports regarding research progress and a copy of the results of on-site investigations conducted by outside experts.

(14) When handling personal information, the director of a research institution shall specify the purpose of using it (hereinafter referred to as the "purpose of use") as much as possible. When changing the purpose of use, the director of the research institution shall not change it beyond the scope reasonably considered as having relevance corresponding to the purpose of use before the change.

(15) Without obtaining the prior consent of the donor, the director of a research institution shall not handle personal information beyond the scope necessary for achieving the purpose of use specified pursuant to paragraph 6(14) of Part II.

(16) When personal information has been acquired as a consequence of taking over research from another research institution on account of a merger or for any other reason, the director of the research institution shall not handle the said personal information beyond the scope necessary for achieving the purpose of use of personal information that was relevant prior to taking over the research without first obtaining the consent of the donors.

(17) When personal information has been acquired, the director of the research institution shall immediately notify the donors of the purpose of use or publicly announce it, except in cases where the purpose of use has already been publicly announced.

(18) When the purpose of use has been changed, the director of a research institution shall notify the donors of the changed purpose of use, or shall publicly announce it.

(19) The director of a research institution shall endeavor to keep personal information accurate and up to date within the scope necessary for achieving the purpose of use.

(20) Except in the following cases, the director of a research institution shall not provide personal information to a third party without obtaining the prior consent of the donor:

(a) When provided by laws and regulations

(b) When it is particularly necessary for the improvement of public health, and it is difficult to obtain the consent of donors

(c) When it is necessary to cooperate with a state organ or local government, or with a person so entrusted, in their execution of affairs prescribed by laws and regulations, and when obtaining the consent of the donors is likely to impede the execution of those affairs

In the following cases, a person receiving such personal information shall not be deemed to be a third party:

(a) When all or part of the handling of personal information is entrusted within the scope necessary for achieving the purpose of use

(b) When personal information is provided as a consequence of taking over research on account of a merger or for any other reason

(c) When personal information is used jointly between specific persons, and when this fact, the items of the personal information used jointly, the scope of the joint users, the purpose for which the personal information is used by them, and the names of the persons responsible for the management of the personal information are, in advance, notified to the donors or made readily available to them

When the director of a research institution changes the purpose for which the personal information is used or the names of the persons responsible for the management of the personal information, as provided in (c) above, the director of the research institution shall, in advance, either notify the donors about the details of the change or shall make them readily available to the donors.

(21) The director of a research institution shall, with respect to any personal information retained, make the following matters available to donors (including cases when responding immediately at the request of a donor):

(a) The name of the relevant research institution

(b) The purpose of use of all retained personal information (excluding cases falling under paragraph 6(22) (a) through (c) of Part II)

(c) Procedures responding to any requests made under paragraph 6(22), (23), (24), (25) or (26) of Part II (including the amount of any charges if set)

(d) Where complaints can be made concerning the handling of retained personal information

(22) When a request is received from a donor or proxy consentor, etc. for notification of the purpose of use of retained personal information by which the relevant donor can be identified, the director of the research institution shall provide notification of this, without delay, to the donor or proxy consentor, etc.

However, this shall not apply to any of the following cases:

(a) When notifying the donor or proxy consentor, etc. of the purpose of use or publicly announcing it is likely to harm the life, body, property or other rights or interests of the donor or a third party

(b) When notifying the donor or proxy consentor, etc. of the purpose of use or publicly announcing it is likely to harm the rights or legitimate interests of the research institution

(c) When it is necessary to cooperate with a state organ or local government in their execution of affairs prescribed by laws and regulations, and when notifying the donor or proxy consentor, etc. of the purpose of use or publicly announcing it is likely to impede the execution of those affairs

When it has been decided to not notify the purpose of use, the director of the research institution shall notify the donor or proxy consentor, etc. of that effect without delay.

(23) When the director of a research institution is requested by a donor or proxy consentor, etc. to disclose retained personal information by which the relevant donor

can be identified (including notifying if there is no such retained personal information by which the relevant donor can be identified; the same shall apply hereinafter), the director of the research institution shall disclose the retained personal information to the donor or proxy consentor, etc. in writing without delay.

However, if disclosure would result in any of the following, the director of the research institution may withhold all or part of the personal information from disclosure:

- (a) When disclosure is likely to harm the life, body, property or other rights or interests of the donor or a third party
- (b) When disclosure would violate laws or regulations

Where the director of a research institution has decided not to disclose all or part of its retained personal information, the director of the research institution shall notify the donors or proxy consentors, etc. of that effect without delay.

<Note>

With regard to the disclosure of genetic information, the research director shall be made responsible for this under section 11 of Part III.

(24) When the director of a research institution is requested by a donor or proxy consentor, etc. to correct, add, or delete such retained personal information by which the donor can be identified on the grounds that the retained personal information is contrary to fact, the director of the research institution shall, except in cases in which special procedures are prescribed by any other laws and regulations for such correction, addition, or deletion, make a necessary investigation without delay within the scope necessary for achieving the purpose of use and, on the basis of those results, correct, add, or delete the retained personal information.

When the director of a research institution has corrected, added or deleted all or part of the retained personal information, or has decided not to make such a correction, addition or deletion, the director of the research institution shall notify the donor or proxy consentor, etc. of that effect (including the details of any correction, addition or deletion) without delay.

(25) Where the director of a research institution is requested by a donor or proxy consentor, etc. to suspend using or to erase retained personal information by which the relevant donor can be identified on the grounds that the retained personal information concerned is being handled in violation of paragraph 6(15) or (16) of Part II or that it has been acquired in violation of paragraph 5(10) of Part II, and where it is found that the request has reason, the director of the research institution shall suspend using or erase the retained personal information concerned without delay to the extent necessary for rectifying the violation.

However, this provision shall not apply to cases in which considerable expenses would be incurred or in which it would otherwise be difficult to suspend using or erase the

retained personal information concerned, and in which necessary alternative measures are taken to protect the rights and interests of donors.

<Detailed regulations concerning suspension of use or erasure>

In these Guidelines, the term “suspension of use or erasure” shall mean taking measures such as the disposal of information upon revocation of informed consent.

(26) Where the director of a research institution is requested by a donor or proxy consentor, etc. to suspend providing to a third party retained personal information by which the relevant donor can be identified on the grounds that the retained personal information concerned is being provided to the third party in violation of paragraph 6(20) of Part II, and where it is found that the request has reason, the director of the research institution shall suspend providing the retained personal information concerned to the third party without delay.

However, this provision shall not apply to cases in which considerable expenses would be incurred or in which it would otherwise be difficult to suspend providing the retained personal information concerned to the third party, and in which necessary alternative measures are taken to protect the rights and interests of donors.

(27) When the director of a research institution has suspended using or erased all or part of the retained personal information as requested under paragraph 6(25) of Part II, or has decided not to suspend using or erase the retained personal information concerned, or when the director of a research institution has suspended providing to a third party all or part of the retained personal information as requested under paragraph 6(26) of Part II, or has decided not to suspend providing the retained personal information concerned to the third party, the director of the research institution shall notify the donor or proxy consentor, etc. of that effect without delay.

(28) When the director of a research institution notifies a donor or proxy consentor, etc. that it will not be taking all or part of the measures as requested by the donor or proxy consentor, etc. pursuant to paragraph 6(22), (23), (24) or (27) of Part II, or that it will take different measures, the director of the research institution shall endeavor to explain those reasons.

(29) The director of a research institution may provide the following matters as the method for receiving requests made pursuant to paragraph 6(22), (23), (24), (25) or (26) of Part II (hereinafter referred to as “request for disclosure, etc.”). In such a case, donors or proxy consentors, etc. shall make any requests for disclosure, etc. in accordance with the said method:

(a) Where requests for disclosure, etc. can be made

(b) The form of any documents to be submitted when making a request for disclosure, etc. (including any records made by electronic, magnetic or any other means not perceptible to human senses) and other formalities for making requests for disclosure, etc.

(c) The method for confirming that the person making a request for disclosure, etc. is a donor or proxy consentor, etc.

(d) The method for collecting charges

(30) The director of a research institution may ask a donor or proxy consentor, etc. making a request for disclosure, etc. to present sufficient items to identify the retained personal data in question. In this case, the director of the research institution shall take appropriate measures that take into account the convenience of the donor or proxy consentor, etc. and the provision of information that is helpful in identifying the retained personal information in question, so that the donor or proxy consentor, etc. can make a request for disclosure, etc. easily and accurately.

(31) In determining the procedures for responding to requests for disclosure, etc. made pursuant to paragraphs 6(29) and (30) of Part II, the director of the research institution shall give consideration to the procedures so that they do not impose an excessive burden on the donor or proxy consentor, etc.

(32) When the director of a research institution is requested to notify the purpose of use under paragraph 6(22) of Part II or to make a disclosure under paragraph 6(23) of Part II, the director of the research institution may collect charges for implementing the measure.

In such a case, the director of the research institution shall determine the amount of the charge within the scope considered reasonable in consideration of actual costs.

(33) The director of a research institution shall respond appropriately and promptly to any complaints, inquiries or the like from donors, etc., such as by setting up a contact point for complaints, etc.

The director of the research institution shall give consideration to the placement of contact persons, procedures for using the service and so on so that the contact point for complaints, etc. is easy for donors, etc. to use.

(34) The director of a human specimen collecting institution shall, in principle, anonymize human specimens when providing them to an external institution.

The director of a human specimen collecting institution shall also, in principle, anonymize human specimens when providing them to a research division conducting human genome/gene analysis research within the human specimen collecting institution (hereinafter referred to as a "research division" within a human specimen collecting institution").

However, when both of the following conditions are met, the director of the human specimen collecting institution may provide human specimens without anonymizing them:

(a) The donors or proxy consenters, etc. agree to human specimens being provided to external institutions or research divisions within the human specimen collecting institution without being anonymized.

(b) A research protocol authorized by the ethics review committee and approved by the director of the research institution allows for the provision of unanonymized human specimens to external institutions or research divisions within the human specimen collecting institution.

(35) The director of a human specimen collecting institution shall, as required, give consideration so that donors and their families or blood relatives will be able to receive genetic counseling such as by establishing an appropriate genetic counseling system or explaining about genetic counseling and referring them to appropriate facilities.

<Detailed regulations concerning referrals to genetic counseling facilities>

Where a human specimen collecting institution does not have an internal genetic counseling system, the institution shall, if requested for such counseling, refer donors and their families or blood relatives to appropriate facilities for genetic counseling.

(36) With regard to the informed consent forms obtained from donors or proxy consenters, etc., the director of the human specimen collecting institution shall have them administered by the research director, privacy officer or other such person at the human specimen collecting institution who is capable of strict management.

7. Responsibilities of research directors

(1) A research director shall, prior to conducting human genome/gene analysis research, prepare a research protocol, and seek approval from the director of the research institution. The same shall apply when the research director intends to change the research protocol.

<Detailed regulations concerning cases when changing a research protocol>

Where a research protocol, including research objectives, has been changed after obtaining the informed consent, section 13 of Part IV (Use of Human Specimens Donated for Future Research) shall apply to any human specimens collected before the change for the purpose of using in the said research.

(2) In preparing a research protocol, the research director shall give careful consideration to such factors as the necessity of the research and a research method to prevent disadvantage to donors, etc., in view of the various impacts that donors, etc. could be expected to experience as a result of the proposed human genome/gene analysis research.

<Detailed regulations concerning cases when donors have an illness involving a mental disorder, intellectual disability or severe physical disability>

When a donor has a single-gene disorder or the like, for which a treatment or prevention method has not been established and which involves a mental disorder, intellectual disability or severe physical disability, the research director shall take particular caution in examining such factors as the necessity of the research, medical/psychological impacts on the donor, and the propriety of the research method proposed, and the ethics review committee shall take particular caution in reviewing such factors.

(3) A research director shall prepare a research protocol in full consideration of the characteristics of human genome/gene analysis research. In particular, the research director shall clearly describe such matters as the process and method of obtaining informed consent, the method of personal information protection, the results expected from the research and the principles of the disclosure, the method of preservation and use of human specimens, and the principles of genetic counseling.

<Detailed regulations concerning matters to be stated in research protocols>

The following items shall, in general, be stated in a research protocol, but adjustments may be made according to the details of the research:

- Donor selection policy (specific selection method which shows that selections are made in a reasonable manner; when a donor has a disease, a drug response abnormality or the like, the means to inform the donor of the disease name or an equivalent description of the condition)
- The significance, objectives and method of research (the targeted disorder, analytical methods and so forth; where future additions and/or alterations are anticipated, a description to that effect; in the case of a single-gene disorder or the like, the necessity of the research, measures for preventing disadvantage and other items worthy of special mention), the period of research, the expected results and risks, and the methods for protecting personal information (including the handling of unanonymized information)
- The types and quantities of human specimens
- The names of the collaborative research institutions
- The names of the research director and so forth
- The procedures and method for obtaining informed consent
- The explanatory document and letters of agreement for obtaining informed consent
- Where obtaining the informed consent of donors is difficult, the importance of the research, the reasons why the research cannot be realized without the donation of human specimens from donors, and the approach to selecting proxy consenters, etc.
- The approach regarding the disclosure of genetic information (including, where necessary, the methods for receiving requests for disclosure)
- Where using human specimens donated for future research, whether or not consent has been obtained, the details thereof, the timing of provision, and the compatibility with these Guidelines
- Where receiving human specimens or genetic information from another research institution, the details of the informed consent
- Where providing human specimens or genetic information or entrusting part of the research to an external institution, such matters as the anonymization method (including details of the contracts concerned)

- The method of preserving human specimens and the necessity for this (including the possibility of using them in other research and the details of the predicted research)
- Where providing human specimens to a human cell, gene or tissue bank, the name of the bank, the anonymization method and so forth
- The method of disposing human specimens and the anonymization method in this case
- The necessity of genetic counseling and the related system
- The method of raising research funds

(4) A research director shall supervise research investigators to ensure that they conduct human genome/gene analysis research properly, such as by having all research investigators observe matters included in an approved research protocol.

(5) A research director shall, with regard to the progress of human genome/gene analysis research, report in writing to the director of the research institution on a regular basis, at least annually.

<Detailed regulations concerning the reported items>

A research director shall, in general, include the following items in their regular reports on research progress submitted to the director of the research institution, but may make adjustments according to the details of the research:

- The quantity of human specimens provided, and the method of retaining human specimens
- The quantity of human specimens or genetic information provided to external institutions, and the reason for such provision
- The quantity of human specimens on which human genome/gene analysis research was conducted
- The research results, the progress of research, and whether or not any problems arose
- In the case of a human specimen collecting institution, in addition to the above, the quantity of anonymized human specimens

(6) When conducting research on a group of people who have certain characteristics, such as a group of local residents (hereinafter referred to as "local residents, etc."), where that research may reveal the genetic characteristics of the local residents, etc., the research director shall explain the details and significance of the research, such as by holding a briefing for the local residents, etc. prior to the research, and shall endeavor to gain the understanding of the local residents, etc. for the research. In addition, during the research, the research director shall endeavor to maintain dialogue with the local residents, etc., such as by providing information on the research.

(7) A research director shall, in principle, conduct human genome/gene analysis research using anonymized human specimens or genetic information.

However, in cases where the donor or proxy consentor, etc. agrees, and where it is permitted in a research protocol authorized by the ethics review committee and

approved by the director of the research institution, the research director may elect to not anonymize the human specimens or genetic information.

(8) A research director shall not, in principle, provide unanonymized human specimens or genetic information to external institutions.

However, in cases where the donor or proxy consentor, etc. agrees to providing unanonymized human specimens or genetic information to an external institution, and where it is permitted in a research protocol authorized by the ethics review committee and approved by the director of the research institution, the research director may provide unanonymized human specimens or genetic information to the external institution.

(9) When entrusting part of the business of human genome/gene analysis research, the research director shall first obtain the authorization of the ethics review committee and the approval of the director of the research institution, and shall indicate this to the trustee in writing.

(10) In cases where part of the business of human genome/gene analysis research has been entrusted, when providing human specimens or genetic information to the trustee, the research director shall, in principle, anonymize those human specimens or genetic information.

However, in cases where the donor or proxy consentor, etc. agrees, and where it is permitted in a research protocol authorized by the ethics review committee and approved by the director of the research institution, the research director may provide unanonymized human specimens or genetic information.

(11) A research director shall, both on a regular basis and in response to any requests from donors, etc., explain or publicly announce the progress and results of the human genome/gene analysis research.

However, this shall not apply to any parts necessary for guaranteeing the human rights of donors, etc. or protecting intellectual property rights.

8. Responsibilities of Privacy Officers

(1) Upon the request of the research director based on a research protocol, a privacy officer (including privacy subofficers; the same shall apply in this section 8 of Part II) shall, in principle, anonymize human specimens or genetic information prior to conducting the human genome/gene analysis research.

However, in cases where the donor or proxy consentor, etc. agrees, and where it is permitted in a research protocol authorized by the ethics review committee and

approved by the director of the research institution, the research director may elect to not anonymize the human specimens or genetic information.

(2) A privacy officer shall not, in principle, provide any personal information that was removed at the time of anonymization to an external institution or a research division within a human specimen collecting institution.

However, in cases where the donor or proxy consentor, etc. agrees, and where it is permitted in a research protocol authorized by the ethics review committee and approved by the director of the research institution, the privacy officer may provide personal information to external institutions and research divisions within a human specimen collecting institution.

(3) In addition to conducting anonymization work, a privacy officer shall also appropriately manage and dispose of any index tables and so forth prepared during the anonymization work, and shall rigorously control any data containing personal information to prevent it from being divulged.

9. Responsibilities and Composition of Ethics Review Committees

(1) An ethics review committee shall, in accordance with these Guidelines, review the appropriateness of conducting a research protocol and other relevant matters, including both ethical and scientific viewpoints, and shall state its opinion in writing to the director of the research institution.

(2) With regard to research in progress, an ethics review committee may state to the director of the research institution its opinion on the alteration or discontinuation of the research protocol or on any other matters it deems necessary.

(3) Members of an ethics review committee shall not, in the absence of any justifiable reason, divulge information obtained in the course of their duties. This shall continue to apply after they resign their position.

(4) An ethics review committee shall be properly composed of and operated by members from various backgrounds so that it can perform reviews in a fair and impartial manner from an independent standpoint, based on an interdisciplinary and pluralistic approach.

<Detailed regulations 1: Detailed regulations concerning the composition of ethics review committees>

- An ethics review committee should be composed of experts in the fields of human/social sciences, including ethics and law, experts in the field of natural science and persons with a general background.

- It is preferable that at least half of the members of an ethics review committee be external persons, but where securing these persons is difficult, the committee should have at least several external members.
- At least half of the external members should be experts in the fields of human/social sciences or persons with a general background.
- An ethics review committee should be composed of both male and female members.

<Detailed regulations 2: Detailed regulations concerning the operation of ethics review committees>

- When an ethics review committee deliberates or votes on an item, at least one member in the fields of human/social sciences or one member with a general background should be in attendance.
- Neither the director of the research institution nor the research director and research investigator of the research under review shall participate in the deliberation or voting of the ethics review committee. They may, however, attend meetings and provide explanations at the request of the ethics review committee.

<Detailed regulations 3: Detailed regulations concerning operating regulations>

Operating regulations shall be established with regard to the following matters:

- The method for selecting the chairperson
- Requirements for convening a meeting
- The method for making decisions
- The retention period for review records
- Matters related to public announcements

(5) An ethics review committee may, according to its decision, establish a fast-track review process to be conducted either by members nominated in advance by the chairperson or by a subcommittee. The results of a fast-track review shall be reported to all members other than those who performed the review or, in case of a subcommittee, to its umbrella organization, the ethics review committee.

<Detailed regulations concerning the fast-track review process>

1. Matters that may be committed to a review through the fast-track review process shall, in general, be as follows:

- The review of minor alterations to a research protocol
- The review of any research protocols classified under the same type as a research protocol already authorized by the ethics review committee
- In the case of collaborative research, the review of a research protocol in cases where another collaborative research institution intends to conduct, with no problems particular to the institution, a research protocol that has already been authorized by the ethics review committee of the principal research institution.

2. An ethics review committee member who has received a report on the results of a fast-track review may, upon giving reasons, ask the chairperson for a separate review by the ethics review committee with regard to the said matter. In this case, the chairperson shall, provided that he/she acknowledges that there are reasonable

grounds to do so, immediately hold an ethics review committee meeting and review the matter.

(6) An ethics review committee shall publicly announce the matters concerning its organization and the rules concerning its operation, and shall, in principle, also publicly announce the details of its proceedings.

<Detailed regulations 1: Detailed regulations concerning the public announcement of matters concerning organization>

The matters to be publicly announced concerning the organization of an ethics review committee shall be as follows:

- The composition of the ethics review committee (including any subcommittees)
- The names of the members, the organizations to which they are affiliated and their positions

<Detailed regulations 2: Detailed regulations concerning the public announcement of proceedings>

1. Proceedings of the ethics review committee should be publicly announced in a specific and clear manner.

2. Any parts of the proceedings which are likely to impede the protection of the human rights of donors, etc., the originality of research or intellectual property rights, or which are likely to impede the preservation of competitive position, may be kept undisclosed on the basis of a decision by the ethics review committee. In such cases, the ethics review committee should publicly announce the reasons for nondisclosure.

PART III: BASIC STANCE TOWARD DONORS

10. Informed Consent

(1) A research director (excluding those who conduct research by receiving human specimens from an external institution or from other divisions within the research institution; the same shall apply hereinafter in section 10 of Part III (excluding paragraphs (9) and (12))) shall not select persons to receive requests for human specimen donation in an unreasonable, improper or unfair manner.

(2) Where a person receiving a request for human specimen donation has or may have a disease or drug response abnormality, that person shall have been informed of the disease name or an equivalent description of the condition.

(3) A research director shall receive the donation of a human specimen after first giving to a donor adequate explanation of such matters as the significance, objectives and method of the research, the expected results, any disadvantage that the donor might incur, and the methods of preserving and using the human specimen, and upon obtaining written consent made on the basis of free will (informed consent).

There shall, however, be no requirement to obtain informed consent in cases where personal information or human specimens need to be received urgently for the protection of the life or body of an individual.

(4) A research director shall not use deception or other wrongful means when obtaining informed consent.

The research director shall also give consideration when receiving the donation of human specimens so as not to make the donor feel anxious.

<Detailed regulations concerning matters to be considered when obtaining informed consent>

The matters to be considered when obtaining informed consent include preventing unnecessary contact with donor information.

(5) In receiving informed consent, the research director shall not harm the life, body, property or other rights or interests of the donor or a third party by notifying the donor or proxy consentor, etc. of the purpose of use of the human specimen or by publicly announcing it.

(6) Where a research director is unable to conduct the work necessary for obtaining informed consent, he/she may have all or part of the work performed, under his/her guidance and supervision, by a researcher, etc. at the human specimen collecting institution who fully understands such factors as the details and significance of the research.

(7) By entering into a contract with a person other than a researcher, etc. affiliated with the institution (hereinafter referred to as an "aide"), which clarifies the scope and responsibilities of work, a research director may have the aide conduct explanations necessary for obtaining informed consent, and may have the aide conduct part of the work necessary for obtaining informed consent.

In such cases, the research director shall include a description to this effect in the research protocol, and, where necessary, shall secure training opportunities for the aides.

<Detailed regulations concerning aides for informed consent>

1. When having someone other than persons affiliated with the human specimen collecting institution obtain informed consent, the research director of the human specimen collecting institution shall include in the research protocol that aides are designated and, where necessary, statements about research methods and so forth, and the said research protocol shall be authorized by the ethics review committee of the human specimen collecting institution and approved by the director of the human specimen collecting institution.

2. Where the research director of the human specimen collecting institution has an aide conduct certain work, including obtaining consent from human specimen donors or proxy consenters, etc., this shall be limited to cases where the aide is in principle, a person, such as a medical doctor or pharmacist, who is prohibited from divulging any confidential information obtained in the course of their duties under Article 134 of the Penal Code, Article 100 of the National Public Service Act or any other law.

(8) Where obtaining the informed consent of donors is difficult, the research director may obtain informed consent from a proxy consenter, etc. of the donor, but only when the importance of the proposed research is high, and when the ethics review committee has acknowledged and the director of the research institution has approved that the research cannot be realized without the donation of a human specimen from the donor.

<Detailed regulations 1: Detailed regulations concerning the handling of cases when informed consent is obtained from a proxy consenter, etc.>

Cases where obtaining the informed consent of a donor is difficult but can be achieved by means of the informed consent of a proxy consenter, etc., and the handling of such cases shall be as follows. In any case, the research director shall include in the research protocol: the importance of the research, the reasons why the research cannot be realized without the donation of human specimens from donors and the approach to selecting proxy consenters, etc., and the said research protocol shall be authorized by the ethics review committee and approved by the director of the research institution:

- When it is judged objectively that the donor is not capable of giving effective informed consent for a reason such as dementia
- When the donor is a minor. In this case, however, a research director shall still give adequate explanation to the donor in plain language and shall endeavor to gain their understanding. When the donor is a minor aged 16 years or older, the research director shall obtain informed consent from both the donor and the proxy consenter.
- When the donor is a deceased person, and there is no contradiction to their explicit wishes made before their death

<Detailed regulations 2: Detailed regulations concerning the basic principles of selecting proxy consenters>

A research director must state their approach to selecting proxy consenters, etc. in research protocols. This shall be on the basis that, in general, people are selected as proxy consenters from among those listed below, who are regarded as being able to represent the presumed intentions and interests of the donor, taking into account such factors as the donor's family composition and the situation in which they are placed:

1. Voluntary guardians, persons who have parental authority, or any guardians or curators if appointed
2. The spouse, adult children, parents, adult siblings or grandchildren, or grandparents of the donor, relatives living with the donor, or other persons considered to be equivalent to these close relatives

<Detailed regulations 3: Detailed regulations concerning the basic principles of selecting surviving family members>

A research director must state their approach to selecting surviving family members in research protocols. This shall be on the basis that, in general, people are selected as surviving family members from among those listed below, who are regarded as being able to represent the presumed intentions of the donor before their death, taking into account such factors as the deceased donor's family composition, the situation in which they were placed and the deceased donor's customs:

- The spouse, adult children, parents, adult siblings or grandchildren, or grandparents of the deceased donor, relatives who were living with the deceased donor, or other persons considered to be equivalent to these close relatives

(9) A donor or proxy consentor, etc. may revoke, in writing, their informed consent at any time without suffering any disadvantage.

(10) Where a donor or proxy consentor, etc. has revoked their informed consent, the research director shall, in principle, anonymize the human specimens and research results related to the said donor and dispose of them, and shall provide notification of this, in writing, to the donor or proxy consentor, etc. The research director shall also comply accordingly if the donor or proxy consentor, etc. requests some kind of measure other than disposal, unless there are exceptional grounds.

However, when any of the following conditions are met, the research director may elect not to dispose of the human specimens and research results:

- (a) When the human specimens concerned have been anonymized in an unlinkable fashion
- (b) When not disposing of the human specimens and research results has been authorized by the ethics review committee and approved by the director of the research institution, due to such circumstances that the risk of personal information being revealed from not disposing of the human specimens and research results is very low and that the work involved in disposing of them is very excessive
- (c) When the research results have already been publicly announced

<Detailed regulations concerning cases when research results have been publicly announced>

Paragraph 10(10)(c) of Part III shall be limited to cases premised on the disposal of human specimens.

(11) The research director of a human specimen collecting institution shall, in the process of obtaining informed consent from a donor or proxy consentor, etc., give explanations to the donor or proxy consentor, etc. by issuing a written document describing the necessary matters in order to obtain an adequate understanding. When a donor has a single-gene disorder or the like (including multifactorial disorders in which the related gene is definite), the research director shall give explanations, including information related to the use of genetic counseling and, as required, offer opportunities for genetic counseling.

<Detailed regulations concerning the content of explanatory documents>

The matters to be included in explanatory documents for donors and proxy consenters, etc. shall, in general, be as follows, but adjustments may be made according to the details of the research:

- That the donation of human specimens is voluntary
- That any person who has received a request for human specimen donation will not be treated in a disadvantageous manner as a result of not agreeing to donate a human specimen
- That a donor or proxy consentor, etc. may revoke, in writing, the informed consent they gave, at any time without suffering any disadvantage (including, where necessary, the methods for receiving requests for revocation)
- That, where consent has been revoked by a donor or proxy consentor, etc., the human specimens and research results related to the said revocation will be disposed of, unless, for instance, they have been anonymized in an unlinkable fashion
- The reasons for selection as a donor
- The significance, objectives and method of research (the targeted disorder, analytical methods and so forth; where future additions and/or alterations are anticipated, a description to that effect; in the case of a single-gene disorder or the like, the necessity of the research, measures for preventing disadvantage and other items worthy of special mention), the period of research
- When personal information is used jointly with other institutions in collaborative research: (i) the fact that it is collaborative, (ii) the items of the personal information used jointly, (iii) the scope of the joint users, (iv) the purpose for which the personal information is used by them, and (v) the names of the persons responsible for the management of the personal information
- In the case of long-term, ongoing research, the research institution's point of view regarding the organization and systems necessary for conducting the ongoing research
- Where obtaining the informed consent of donors is difficult, the importance of the research and the reasons why the research cannot be realized without the donation of human specimens from donors
- The name and position of the research director
- The predicted research results and any predicted risks and/or disadvantages to a donor, etc. (including any disadvantages in social life, such as social discrimination)
- That a donor or proxy consentor, etc. may, upon request, obtain or inspect documents on the research protocol and research method to the extent that doing so does not impede the protection of personal information of other donors, etc. or the securing of research originality
- Whether a donated human specimen or the genetic information derived therefrom will be anonymized in a linkable or unlinkable fashion, and the specific method of anonymization; when anonymization is not possible, a description to this effect and the reasons for this
- Whether or not a human specimen or the genetic information derived therefrom can be provided to other institutions; and if so, that the ethics review committee would review the handling of personal information, the names of the receiving institutions, and that the purposes of use at the receiving institutions are appropriate

- The anonymization method, etc. when part of the research is entrusted
- Matters regarding the disclosure of genetic information (if not disclosed, the reasons therefor)
- Matters regarding the disclosure of personal information (including where and how requests for disclosure are received, the method for confirming that a person is a donor or proxy consentor, etc., and if charges are incurred for disclosure, a description to this effect)
- That research outcomes might generate intellectual property rights, such as patent rights, in the future; the names of any envisaged organizations to which such intellectual property rights, such as patent rights, would belong, were they to be generated
- That genetic information derived from human specimens might, upon anonymization, be publicly announced in an academic society, etc.
- The methods of preserving and using the human specimens
- The method of preservation, use or disposal of human specimens after the completion of research (including the possibility of using them in other research and the details of the predicted research)
- When human specimens might be provided to a human cell, gene or tissue bank for division and distribution as general research resources, the academic significance of the bank concerned, the name of the organization operating the bank, the method of anonymization for the human specimens being provided, and the name of the responsible person at the bank
- Information related to the use of genetic counseling (for instance, that genetic counseling is available in the case of single-gene disorders or the like)
- The method of raising research funds
- That the donation of human specimens is without compensation
- Information regarding the address and other details of contact points for inquiries (for instance, the correction of personal information and the revocation of consent) and complaints, etc.

(12) A research director receiving human specimens or genetic information from another research institution shall confirm the details of the informed consent related to the human specimens or genetic information by such means as a written document from that research institution.

(13) Prior to conducting human genome/gene analysis research, when a research director obtains informed consent from a donor or proxy consentor, etc. with the expectation that the human specimen and/or genetic information will be used in human genome/gene analysis research or related medical research, the research director shall clearly state the specific research objectives expected at that point in time, and shall explain to and gain the understanding of the donor or proxy consentor, etc. regarding how personal information will be controlled and protected, including the possibility of anonymization.

11. Disclosure of Genetic Information

(1) With regard to human genome/gene analysis research through which the genetic information of individual donors is revealed, when a donor has requested disclosure of his/her own genetic information, the research director shall, in principle, disclose the requested information.

However, when providing genetic information is likely to harm the life, body, property or other rights or interests of the donor or a third party, and when the informed consent of the donor regarding nondisclosure has been received, the research director may withhold all or part of the genetic information from disclosure.

When the genetic information is not disclosed, the research director shall explain the reasons for nondisclosure to the donor.

<Detailed regulations concerning the disclosure of genetic information>

1. Given the possibility that it may not necessarily be appropriate to provide donors with an explanation, such as possible instances of psychological burden on a donor resulting from notification of the reason for nondisclosure, the research director shall respond after careful consideration according to circumstances.

2. When, despite having agreed to the nondisclosure of genetic information at the time of giving his/her informed consent, a donor requests disclosure after the fact, the research director shall, except in the following case, disclose the donor's genetic information:

- In the case of human genome/gene analysis research that is attempting to reveal the function of a certain gene or the association between genes and a certain disorder by mutually comparing the genetic information of a large number of people or genes, where the information is not accurate or certain enough to evaluate the state of the person's health, and the research protocol contains a statement on how genetic information will not be disclosed because of the likelihood of disclosure resulting in harm to the life, body, property or other rights or interests of the donor or a third party, and where this research protocol has been authorized by the ethics review committee and approved by the director of the research institution

3. When a donor, who is a minor, has requested disclosure of his/her own genetic information, the research director may disclose the information to the minor upon adequate consideration of potential psychological impacts etc. of disclosure.

Where, however, the minor is under the age of 16 years, the research director shall check the intention of the donor's proxy consentor and respect that intention.

The research director shall also report to the director of the research institution when, as a result of disclosing the minor's genetic information, the donor might injure himself/herself or there is concern about discrimination against the donor, denial of fostering or negative impacts on treatments. The director of the research institution shall, prior to disclosure, seek opinions of the ethics review committee where necessary and

also seek dialogue with the minor and his/her proxy consentor, before making a decision regarding the propriety of disclosure and the details and method thereof.

4. Where the research director has decided not to disclose the genetic information, the research director shall notify the donor who requested the disclosure of that effect in writing.

(2) With regard to human genome/gene analysis research through which the genetic information of individual donors is revealed, when a donor has not requested disclosure of his/her own genetic information, the research director shall not disclose the requested information.

<Detailed regulations concerning the nondisclosure of genetic information>

A research director shall, even if a donor has not requested disclosure of his/her own genetic information, report to the director of the research institution when it is discovered that the genetic information has a serious impact on the life of the donor and his/her blood relatives and, at the same time, there is an effective treatment protocol.

The director of the research institution shall seek the opinions of the ethics review committee regarding the propriety of disclosure and the details and method thereof, including consideration of, in particular, the following matters, and shall, based on those opinions, consult with the research director, the medical doctor in charge of the donor's medical care and the director of the medical institution to which the doctor belongs. The research director shall, based on the results of the consultation, check the intention of the donor after giving him/her adequate explanations and, if the donor still does not want the genetic information to be disclosed, shall not disclose it:

- The impact on the life of the donor and his/her blood relatives
- Whether or not there is an effective treatment protocol, and the donor's state of health
- The possibility that blood relatives are afflicted with the same disorder etc.
- Details of the explanation on the disclosure of research results given at the time of the informed consent

(3) A research director shall not, in the absence of consent from the donor, in principle, disclose the donor's genetic information to any person other than the donor.

<Detailed regulations concerning disclosure to persons other than the donor>

1. Where a proxy consentor (excluding persons in 2. and 3.) requests disclosure of the donor's genetic information, the director of the research institution shall, after presenting to the ethics review committee the reasons for or the necessity of the disclosure request by the proxy consentor, determine a response based on the opinions of the ethics review committee. In making this determination, the director of the research institution shall confirm that either of the following conditions has been met:

1) Where there is a requirement for the protection of the life, body or property of an individual, it is difficult to obtain the consent of donors

2) Where there is a particular requirement for the improvement of public health, it is difficult to obtain the consent of donors

2. Where a surviving family member (blood relative) requests disclosure of the donor's genetic information, the director of the research institution shall, after presenting to the ethics review committee the reasons for or the necessity of the disclosure request by the surviving family member (blood relative), determine a response based on the opinions of the ethics review committee.

3. In cases where a donor is a minor and his/her proxy consentor has requested disclosure of the minor's genetic information, the research director may disclose the information to the proxy consentor. Where, however, the minor is aged 16 years or older, the research director shall check the intention of the minor and respect that intention. The research director shall also report to the director of the research institution when, as a result of disclosing the minor's genetic information, there is concern about discrimination against the donor, denial of fostering or negative impacts on treatments. The director of the research institution shall, prior to disclosure, seek opinions of the ethics review committee where necessary regarding the propriety of disclosure and the details and method thereof, and shall seek dialogue with the minor and his/her proxy consentor.

4. Even if a donor has not requested disclosure of his/her own genetic information to blood relatives, when all of the following conditions are met, a research director may convey to the donor's blood relatives information regarding any drug responses or disorders having a genetic predisposition derived from the donor's genetic information:

1) It is discovered that the donor's genetic information is highly likely to have a serious impact on the life of the donor's blood relatives and, at the same time, there is an effective treatment protocol.

2) The director of the research institution, who has received a report set forth in 1) from a research director, seeks opinions of the ethics review committee regarding the propriety of disclosure and the details and method thereof, including consideration of, in particular, the following matters, and, based on those opinions, reaches a conclusion, upon consultation with the research director, that necessary information should be provided to blood relatives:

(a) The possibility that blood relatives are afflicted with the same disorder etc.

(b) The impact on the life of the blood relatives

(c) Whether or not there is an effective treatment protocol, and the blood relatives' state of health

(d) Details of the explanation on the disclosure of research results given at the time of the informed consent

3) In view of the conclusion reached in 2), the research director seeks the understanding of the donor again, and endeavors to obtain consent regarding the provision of necessary information to the blood relatives

4) The intention of the donor's blood relatives to request that information be provided is checked after giving an adequate explanation

(4) A research director shall, when planning to disclose genetic information regarding a single-gene disorder or the like, disclose the information in adequate consideration of the medical or psychological impacts while keeping in close contact with the medical doctor in charge of medical care, and shall also, if necessary, offer opportunities for genetic counseling.

<Note>

The significance of the genetic information being disclosed depends largely on the medical care, and it is necessary to have close contact with the medical doctor in charge of medical care, especially a doctor specializing in medical genetics. Therefore, the person who should disclose the information might be either the medical doctor in charge of medical care who would disclose it as a part of their medical care at the request of the research director, or the research director who would do so under the direction of the medical doctor.

12. Genetic Counseling

(1) Objectives

The objective of genetic counseling in human genome/gene analysis research is to support or assist a donor and his/her family or blood relatives through dialogue so that they can make choices and take action for their future of their own free will, by providing them with accurate information, answering their questions appropriately, deepening their understanding of their hereditary disorder, etc., and answering their anxieties or worries concerning human genome/gene analysis research, hereditary disorders and so forth.

(2) Method of counseling

Genetic counseling shall be provided by and in cooperation with medical doctors, health care professionals and others who have an adequate knowledge of medical genetics and who are proficient in genetic counseling.

<Note>

Matters regarding the establishment of a genetic counseling system for reference to directors of human specimen collecting institutions are prescribed in paragraph 6(35) of Part II, matters regarding the description of principles of genetic counseling in research protocols are prescribed in paragraph 7(3) of Part II, matters to be explained and matters regarding the provision of opportunities for genetic counseling at the time of obtaining informed consent are prescribed in paragraph 10(11) of Part III, and matters

regarding the provision of opportunities for genetic counseling at the time of disclosing genetic information are prescribed in paragraph 11(4) of Part III.

PART IV: HANDLING OF HUMAN SPECIMENS

13. Use of Human Specimens Donated for Future Research

(1) The propriety of using a human specimen provided and preserved before the conduct of any human genome/gene analysis research shall be determined, in accordance with the provisions under (2) to (5) and upon authorization from the ethics review committee, by the director of the research institution with consideration of whether or not consent has been obtained from the donor or proxy consentor, etc., details thereof and the timing of provision of the specimen.

(2) With regard to any human specimens donated for future research after the enforcement of the former guidelines, the director of the research institution and the research director shall carefully form a judgment on their use, and the ethics review committee shall carefully review the propriety of their use in research, in accordance with the principles of these Guidelines.

<Note>

The effective date of the former guidelines is April 1, 2001.

(3) A Group A human specimen (a human specimen for which consent, including consent for its use in human genome/gene analysis research, was obtained at the time of donation) may be used in human genome/gene analysis research within the scope of the obtained consent.

<Detailed regulations concerning the use of Group A human specimens>

The director of a research institution and the research director shall confirm that the consent at the time a Group A human specimen was donated was given for the same research objectives as the research objectives of the new human genome/gene analysis research proposed to be conducted using the specimen in question.

With regard to using a Group A human specimen in other human genome/gene analysis research, the director of the research institution and the research director shall also form judgment as to the extent to which the original consent referred to the significance, research objectives, method of anonymization etc. of the other human genome/gene analysis research, and also with regard to the timing of when the original consent was obtained.

The ethics review committee shall also review how its use should be handled in consideration of similar matters.

(4) A Group B human specimen (a human specimen for which consent has been obtained at the time of donation, but only for research where its use in human genome/gene analysis research has not been clearly stated) may not, in principle, be used in human genome/gene analysis research unless consent from the donor or proxy consentor, etc. is obtained.

This shall, however, not apply to cases where any of the following conditions are met and where such use is both authorized by the ethics review committee and approved by the director of the research institution:

(a) Cases where there is no chance of risk and/or disadvantage befalling the donor, etc. because the specimen has been anonymized in an unlinkable fashion

(b) Cases where the specimen has been anonymized in a linkable fashion, and the consent given at the time the Group B human specimen was provided can be reasonably considered as having relevance corresponding to the objectives of the human genome/gene analysis research, and where the objectives of the human genome/gene analysis research have been notified to the donor or publicly announced.

<Detailed regulations concerning the use of Group B human specimens>

With regard to paragraph 13(4)(b) of Part IV, when notifying the donor of the research objectives of the human genome/gene analysis research or publicly announcing it is likely to harm the life, body, property or other rights or interests of the donor or a third party, there shall be no requirement to notify the donor of the research objectives of the human genome/gene analysis research or to publicly announce it.

(5) A Group C human specimen (a human specimen for which consent for its use in research has not been given at the time of donation) may not, in principle, be used in human genome/gene analysis research unless consent for its use in human genome/gene analysis research is obtained from the donor or proxy consentor, etc.

This shall, however, not apply to cases where any of the following conditions are met and where such use is both authorized by the ethics review committee and approved by the director of the research institution.

In the case of a Group B human specimen, where the consent given at the time of the provision cannot be reasonably considered as having relevance corresponding to the objectives of the human genome/gene analysis research, that specimen shall be deemed to be a Group C human specimen.

(a) Cases where there is no chance of risk and/or disadvantage befalling the donor, etc. because the specimen has been anonymized in an unlinkable fashion

(b) Cases where the specimen has been anonymized in a linkable fashion, and where all of the following conditions have been met:

- (i) The chance of risk and/or disadvantage befalling the donor, etc. as a result of the human genome/gene analysis research is very low
 - (ii) Human genome/gene analysis research using that human specimen is necessary for the improvement of public health
 - (iii) Conducting the human genome/gene analysis research in another way is virtually impossible
 - (iv) Measures have been taken to have information on the progress of human genome/gene analysis research publicly announced and also to guarantee opportunities for donors, proxy consenters, etc. to make inquiries and/or refuse the use of the human specimen in research.
 - (v) It is difficult to obtain the consent of the donor or proxy consentor, etc.
- (c) When provided by laws and regulations

14. Methods for Preserving and Disposing of Human Specimens

(1) General principles for preservation

When preserving a human specimen in a research institution, the research director shall observe matters agreed to by the donor or proxy consentor, etc. and comply with a method prescribed in the research protocol.

(2) Provision to human cell, gene or tissue banks

When providing a human specimen to a human cell, gene or tissue bank, the research director shall confirm that the human specimen will be anonymized in an unlinkable fashion when the bank distributes it as a human specimen for general research, and shall also observe matters agreed to by the donor or proxy consentor, etc., including consent for provision to such banks.

(3) Disposal of human specimens

When the retention period for a human specimen prescribed in a research protocol expires, the research director shall observe matters agreed to by the donor or proxy consentor, etc. and dispose of the human specimen after anonymizing it, except when the research director is preserving the human specimen in accordance with a research protocol or the specimen is provided to a human cell, gene or tissue bank.

PART V: REVISION

15. Revision

These Guidelines shall be revised, as required or approximately five years after they come into force, upon conducting an examination of the entire contents.

PART VI: DEFINITIONS OF TERMS

16. Definitions of Terms

(1) Human specimen

The term “human specimen” shall mean any blood, tissue, cell, body fluid or excrement to be used in human genome/gene analysis research, and any portion of a human body such as DNA extracted therefrom, as well as medical information of a donor or other information used in research (including specimens related to deceased persons).

Any tissue, cell, body fluid and excrement as well as DNA and so forth extracted therefrom, whose scientific value is fixed and, at the same time, whose research achievements are fully recognized, and which is used commonly and broadly in research and is commonly available shall, however, be excluded.

<Note 1>

With regard to the donation of human specimens from persons determined to be brain-dead under the Act on Organ Transplantation (Act No. 104 of 1997), it is assumed that it would be sufficient to receive the donation of human specimens through the removal of organs once the so-called “three indications of death” have been reached, namely, absence of heartbeat, absence of breathing and dilation of pupils.

<Note 2>

With regard to conducting research by receiving the provision of fertilized eggs, embryos, fetuses, ES cells and the like, although taking the purport of these Guidelines into account is necessary, separate careful examination such as from an ethical point of view is also required. It is not the purport of these Guidelines that it would be appropriate to conduct such research solely on the basis of fulfilling these Guidelines.

(2) Medical information

The term “medical information” shall mean information including disease names, drug names, examination results, etc. which are obtained in the course of diagnosis and treatment.

(3) Human genome/gene analysis research

The term “human genome/gene analysis research” shall mean research conducted using human specimens in an attempt to elucidate the structures or functions of the human genome and genes that commonly exist in the cells making up individual donors and which are possibly inheritable. This also includes instances where human specimens are simply provided for use in such research.

With regard to clinical trials and post-marketing surveillance of pharmaceutical products conducted in accordance with the Pharmaceutical Affairs Act (Act No. 145 of 1960) or clinical trials and post-marketing surveillance conducted for the purpose of applying for approval for the manufacture or import of medical devices, since, pursuant to this Act, these are already regulated by the “Ordinance for Implementation Standards for Clinical Tests of Drugs (Ordinance of the Ministry of Health and Welfare No. 28 of 1997)” and

the “Ordinance for Standards for the Post-Marketing Surveillance of Medicine (Ordinance of the Ministry of Health and Welfare No. 10 of 1997),” these Guidelines shall not apply.

<Detailed regulations concerning the scope of human genome/gene analysis research subject to these Guidelines>

1. These Guidelines shall apply to human genome/gene analysis research intending to analyze the structures or functions of base sequences of DNA or complementary DNA derived from mRNA or the like by using leukocytes and other such tissue of a donor, a main example of which is research that analyzes what is called germline mutation or polymorphism. On the other hand, these Guidelines shall not, in principle, apply to research that targets mutation of a genome or a gene that appears *a posteriori* only on an affected region of a disease, such as cancer, and is not inherited by the next generation (this refers to research that analyzes what is called somatic mutation, which includes research that analyzes normal tissues to corroborate the existence of a mutation), research regarding gene expression or research regarding the structures or functions of proteins. When, however, the aforementioned research is conducted for the purpose of elucidating information regarding a genome or a gene to be possibly inherited by descendants, these Guidelines shall apply. Appropriate measures should still be taken, based on the purport of these Guidelines, in conducting research regarding somatic mutation, gene expression or the structures or functions of proteins to which these Guidelines do not apply.

2. In cases where, during the course of conducting any research indicated in paragraph 1. to which these Guidelines do not apply, genetic information (including any human specimens used in obtaining the genetic information) is obtained by reason of chance, the treatment of such specimens, such as their use for human genome/gene analysis research objectives, their appropriate management (security control measures in cases where they fall under personal information, and appropriate handling in cases of anonymized information that does not fall under personal information), their preservation, and their anonymization and disposal, shall be determined by the director of the research institution in consultation with the ethics review committee.

3. Research, whose main objective is not to conduct human genome/gene analysis research but which partially involves human genome/gene analysis research, and research, which secondarily uses a human specimen or genetic information obtained in the course of medical care, shall also be included in the definition.

4. These Guidelines shall not apply to genetic structure analysis training, such as biology training for educational purposes, which is conducted in the study of a gene region whose structure and function is already known and, at the same time, does not involve the use of a human specimen or analysis results beyond training purposes. However, even in cases where gene analysis is conducted for these purposes, appropriate measures should still be taken based on the purport of these Guidelines.

(4) Genetic information

The term “genetic information” shall mean information possibly inherited by descendants which reflects the genetic characteristics or constitution of an individual person, which is obtained in the course of human genome/gene analysis research conducted using a human specimen or which is already contained in a human specimen.

(5) Anonymization

The term “anonymization” shall mean to remove, in part or in whole, from the personal information of a certain person, information through which a specific individual could be identified and to give instead a symbol or a number that has no relevance to the person, for the purpose of preventing the personal information of a donor from being divulged externally in violation of laws and regulations, these Guidelines or a research protocol. When it is impossible to identify a specific person only through a certain piece of information included in a human specimen but it is possible to identify the donor by combining information available elsewhere, such as in some list, “anonymization” shall mean to remove, in part or in whole, the information that is necessary to complete such combination and to make it impossible to identify the donor. Anonymization would be implemented in either of the following ways:

(a) Anonymization in a linkable fashion

Anonymization based on a method where an index table of symbols or numbers attached to donors is maintained so that the donors may be identified as necessary

(b) Anonymization in an unlinkable fashion

Anonymization based on a method where no index table like that in (a) above is maintained so that individual donors cannot be identified

(6) Privacy officer

The term “privacy officer” shall mean a person in charge of controlling and anonymizing personal information at an institution in which personal information is handled, including human specimen collecting institutions, under the direction of the director of the institution so that the personal information of donors, etc. is not divulged outside the institution.

(7) Informed consent

The term “informed consent” shall mean consent regarding the provision and handling of a human specimen which a person, who has been requested to provide a human specimen, gives on the basis of his/her free will after receiving adequate prior explanations from a research director with regard to human genome/gene analysis research and understanding the significance, objectives and method of the research, the expected results and the disadvantages. Under these Guidelines, informed consent is required to be given in writing.

(8) Proxy consentor, etc.

The term “proxy consentor, etc.” shall mean a person who gives informed consent in place of a donor when the said donor is incapable of giving informed consent. When a donor is a deceased person, this term shall mean a surviving family member.

When surviving family members are to be excluded from the definition, the expression “proxy consentor” shall be used.

<Note>

As a proxy consentor, etc. is, first and foremost, a person who decides whether or not to agree to the donation of a human specimen in place of the donor from a viewpoint of protecting the human rights of the donor, separate measures need to be examined with regard to the genetic issues of the proxy consentors, etc. themselves.

(9) Research institution

The term “research institution” shall mean an institution or individual business operator that conducts human genome/gene analysis research (including human specimen collecting institutions).

<Detailed regulations concerning research institutions>

Institutions that conduct human genome/gene analysis research shall be juridical persons and administrative organs (as prescribed in Article 2 of the Act on the Protection of Personal Information Held by Administrative Organs).

(10) Human specimen collecting institution

The term “human specimen collecting institution” shall mean a research institution, such as a medical institution or health center, which collects human specimens from people.

<Detailed regulations concerning human specimen collecting institutions>

In cases where a single university or similar type of corporation has both divisions that conduct research and divisions that collect human specimens, the said corporation shall be a human specimen collecting institution.

(11) Collaborative research institution

The term “collaborative research institution” shall mean a research institution that collaboratively conducts human genome/gene analysis research described in a research protocol. When a research institution receives a human specimen from a separate human specimen collecting institution, the human specimen collecting institution shall also be included in the definition.

<Detailed regulations concerning the handling of personal information between collaborative research institutions>

Where personal information is to be shared between collaborative research institutions stated in a research protocol, a description to that effect, the items of personal information to be shared, the purposes of use and the personal information controls adopted by the users shall be notified in advance to the donor, or made readily available to them.

(12) External institution

The term “external institution” shall mean a research institution or the like other than the research institution to which the researcher, etc. conducting the human genome/gene analysis research belongs.

(13) Ethics review committee

The term “ethics review committee” shall mean a council-type body established as an advisory board to the director of a research institution for the purposes of investigation and discussion of the propriety of conducting human genome/gene analysis research and other related matters, involving both ethical viewpoints, such as guaranteeing the human rights of donors, etc., and scientific viewpoints.

(14) Researcher, etc.

The term “researcher, etc.” shall mean a person in a research institution who is involved in human genome/gene analysis research, such as research directors, research investigators (including those who conduct work receiving the donation of human specimens), persons who conduct genetic counseling, persons who conduct work protecting personal information, and directors of research institutions.

(15) Research director

The term “research director” shall mean a researcher in a research institution who carries out human genome/gene analysis research as well as supervises the operations related to the research protocols, and, at the same time, has sufficient knowledge of the usefulness and limitations of human genome/gene analysis research and of bioethics.

(16) Research investigator

The term “research investigator” shall mean a person who conducts human genome/gene analysis research in accordance with the direction or entrustment of a research director and, at the same time, has the necessary knowledge and skills according to the details of the operation concerned, such as researchers, medical doctors, pharmacists, nurses and clinical laboratory technologists.

(17) Donor

The term “donor” shall mean a person who provides a human specimen for human genome/gene analysis research. When a person who could possibly have relevance to the genetic information of a donor, including his/her family, blood relatives or proxy consentor, etc., is to be included in the definition, the expression “donor, etc.” shall be used.

(18) Genetic counseling

The term “genetic counseling” shall mean targeting, supporting or assisting in the solution or relief of various medical or psychological problems that could arise with regard to a hereditary disorder, through repeated dialogue and provision of information, by making use of knowledge of medical genetics and counseling techniques.

(19) Human specimen donated before starting a research

The term “human specimen donated before starting a research” shall mean a human specimen provided and preserved prior to the conduct of human genome/gene analysis research in a research institution. Human specimens donated for future research can be divided into the following categories, according to the specification of the purpose of use and the extent of consent obtained at the time of human specimen donation:

(a) Group A human specimen

The term “group A human specimen” shall mean a human specimen, the use of which in human genome/gene analysis research has been clearly expressed to the donor as the purpose of use, and for which consent has been given for using the human specimen for this purpose.

(b) Group B human specimen

The term “group B human specimen” shall mean a human specimen, the use of which in human genome/gene analysis research has not been clearly expressed to the donor as the purpose of use, but for which consent has been given at the time of donation, but only for research that does not clearly express the use for the said purpose, as in the phrase “I agree to the specimen being used in medical research.”

(c) Group C human specimen

The term “group C human specimen” shall mean a human specimen for which consent for using the specimen in research has not been given at the time of donation, regardless of whether its use in research has been clearly expressed to the donor as the purpose of use.

(20) Human cell, gene or tissue bank

The term “human cell, gene or tissue bank” shall mean a non-profit business that conducts quality control of provided human cells, genes, tissues and the like, and distributes them to many and unspecified researchers as research resources.

PART VII: DETAILED REGULATIONS

17. Detailed Regulations

In addition to those detailed regulations prescribed in these Guidelines, necessary matters concerning the enforcement of these Guidelines shall be separately prescribed.

PART VIII: EFFECTIVE DATE

18. Effective Date

These Guidelines shall come into effect as of April 1, 2005.